The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

July 14, 2003 – Meeting #9

Day 1 – July 14, 2003

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on July 14, 2003, at the Centers for Medicare and Medicaid Services (CMS) headquarters building in Baltimore, Maryland for its last meeting. Prior to the start of the meeting, CMS staff met in a caucus to discuss various issues related to the negotiations. At approximately 10:25 a.m., the CMS staff joined the committee (Attachment 9.1 – Sign-in Sheet) as Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) called the meeting to order. Mr. Lobel reviewed the minutes from the last meeting with the committee. The minutes were approved as noted (Attachment 9.2). Robert Loyal, Director of Division of Provider Supplier Enrollment, CMS addressed the committee, asking for its cooperation in reaching a consensus and thanking them for their patience during the morning caucus that delayed the start of the session. He further stated that CMS believed a consensus was possible and without it, CMS would be likely to employ assistance from its staff in attendance, as well as others working in higher levels within CMS, to develop the rule on the special payment provisions.

Mr. Lobel distributed copies of a proposed final resolution of the negotiated rulemaking (Attachment 9.3) and requested that the committee review the document and consider what changes, if any, were needed for its approval. Mr. Lobel emphasized the importance of today's meeting. He stressed that negotiations can be successful if everyone is a little unhappy. He stated that he believed that the proposal put together by CMS included advantages and disadvantages to all groups, but must be looked at a totality and as a proposal that binds CMS. He stressed that if consensus is not reached, all sorts of other factors may be taken into account and the certainty that consensus brings is no longer possible. He further noted that when regulatory negotiations are successful, agencies are more likely to utilize them again for other issues. But when they are unsuccessful, he added, they are typically not considered for future use. Mr. Lobel distributed copies of a proposed final resolution of the negotiated rulemaking (Attachment 9.3) and requested that the committee review the document and consider what changes, if any, were needed for its approval. He noted that when regulatory negotiations are successful, agencies are more likely to utilize them again for other issues. But when they are unsuccessful, he added, they are typically not considered for future use. Ms. Sylvester informed the group that the proposed final resolution of the negotiated rulemaking package was comprised of three documents: the Agreement, Committee Statement, and CMS Statement of Intent. She also added that while not reflected in the document CMS rejected the previous proposal by the National Orthotic Manufacturers Association (NOMA) to accept FDA

requirements/standards for facilities as a "third pathway" for the Secretary's accreditation and approval for manufacturers. The committee was given an extended lunch break to caucus and review the proposed agreement.

Following lunch, the committee reviewed the proposed package page-by-page for items that needed clarification and for simple editorial comments. The following items were noted on the Agreement document:

- The facilitators agreed to include a timeframe for the committee to review the draft Notice of Proposed Rulemaking and provide comments to CMS, as well as provide a timeframe for CMS to respond to the comments, before the rule is forwarded for Departmental clearance. It was also noted that individual members of the public could make comments to CMS prior to implementation of the rule, and members of the committee could comment after the final rule was adopted.

- Editorial changes to item seven were made so that it reads, "Each party agrees not to take any action to inhibit the adoption of the proposed rule as final to the extent the final regulations and the preamble have the same substance and effect as the Committee Statement and the CMS Statement of Intent."

- Spellings of committee organizations were changed to make them accurate.

In regards to the Committee Statement, CMS fielded concerns and clarified issues raised by committee members. Changes to this document included:

- The first item was modified to reference all HCPCS codes in the paragraph.

- The third item was modified to specifically reference orthotic HCPCS codes.

- Item 4a was modified by adding the sentence, "However, if the billing entity is a Medicare provider that is not required to have a DMEPOS number, then the billing entity bills under current Medicare rules."

- The second paragraph of item 4c was modified by deleting the words "…it is not required to have a DMEPOS supplier number."

- Item 8 was changes to read, "…fabricated and furnished by individuals certified or facilities accredited by…" CMS also clarified that item 8 does apply to Section 427(a), paragraph F, subparagraph iii, numbers II and III of BIPA 2000.

Among the other issues raised included:

- Do the HCPCS L-codes cover gait training?

- If a manufacturer employs a qualified practitioner(s) who does or oversees fabrication, and the manufacturer meets DMEPOS standards (is DMEPOS supplier), can the manufacturer bill for the item?

- Possibly deleting item 10(c).

- Adopting a better definition "template" in item 10(d).

When the committee reviewed the third document, the CMS Statement of Intent, the second item was changed to read, "For the purposes of these regulations, pertinent to the Medicare special payment provisions of Section 427 of BIPA, CMS shall specify in the text of the NPRM that the terms qualified physical therapist and qualified occupational therapist are synonymous with the definitions physical therapists and occupational therapists found in 42 CFR 484.4.

Following the review of the three documents, the committee held a caucus to review items 5, 6, and 7 of the Committee Statement more closely. Following the caucus, the facilitators drafted additional language for the committee to consider:

- In all cases, the protheses and listed custom-fabricated orthoses must be furnished by a qualified practitioner. A qualified practitioner must be available to fit, adjust the item for the requisite 90-day period and must have a continuing responsibility (i.e., employee, contractor, or contracting physician) for fitting, adjusting, and repair with the billing entity.

- If a qualified practitioner chooses to deal with a non-qualified supplier, CMS will only pay the qualified practitioner. If a qualified practitioner deals with a qualified supplier, billing can be done through either the qualified practitioner or qualified supplier, but not both.

As the committee considered the text above, Michael Brnicick, National Commission on Orthotic and Prosthetic Education, suggested that the group conclude the negotiations, noting that they would not reach consensus on the key issues of qualified practitioner and qualified supplier. Specifically, he stated that he had not changed his mind on this issue since the first meeting and believes the occupational therapists and physical therapists must have additional training to provide custom fabricated orthotics. A number of committee members agreed with Mr. Brnicick's comment, Ms. Sylvester noted that the proposal before the committee was a well balanced agreement in that it had something in it for every group around the table. She said that in a good negotiation no one party comes away with everything they wanted. A negotiation where one party walks away with everything is usually one-sided, not reflective of the give and take necessary in negotiation. She expressed disappointment that some groups seemed to have come to the negotiation with the intent of not agreeing despite assurances that they would negotiate in good faith. She noted that during the convening process all of the groups enthusiastically sought to become members of the committee, in fact, some groups fought to be included. Ms. Sylvester continued, that the organizations who sent representatives spent

considerable money, time and resources; surely they expected that their representatives conduct themselves in a professional manner and work toward an agreement. She hoped that no member of the committee would take pride in the failure of the negotiations. In the end, Ms. Sylvester reminded the committee of the risks of failing to reach agreement, which is the possibility that when CMS promulgates the rule some dearly held positions would not make it into the rule and others disliked positions would become a part of the regulation. The facilitators questioned if any of the organizational representatives were actually prepared to compromise on their positions.

Various committee members expressed their individual views on the likelihood of the group reaching consensus, and CMS re-emphasized its hopes for the committee to reach an agreement. Harley Thomas of the Paralyzed Veterans of America spoke of his disappointment in some committee members' inability to see past their own self interests for the greater good. He lamented the personal attacks causing some irreparable harm between professional groups. Tony Barr of the Barr Foundation added that by not reaching an agreement the committee was doing a disservice to the industry and to the patient. He said one of the purposes of the reg-neg was to protect the patient and by not reaching agreement the committee failed to do so. Finally, due primarily to the lack of resolution on the issues of qualified practitioner and qualified supplier, it appeared that the negotiated rulemaking was over. The facilitators asked for one last caucus with the O&P groups, shortly thereafter Committee members were asked to sign a release statement that documented the group's failure to reach consensus (Attachment 9.9). They were told that CMS' Robert Loyal and Theresa Linkowich would accept closing statements from each organization through August 31, 2003, for inclusion in the final record. Bob Loyal, Director of Division of Provider Supplier Enrollment thanked the committee for its hard work on the proposed rule.

The meeting was adjourned shortly before 5:20 p.m.

List of Attachments

Attachment 9.1	Sign-in Sheet
Attachment 9.2	Approved Meeting Minutes #8
Attachment 9.3	Package (Agreement, Committee Statement, CMS Statement of Intent)
Attachment 9.4	Closing Statement for IL and FL Licensure Boards
Attachment 9.5	Memorandum from Jeffrey G. Schneider, Hogan & Hartson, LLP
Attachment 9.6	Memorandum from Julie Kass, OBER/KALER Attorneys at Law, to the American Occupational Therapy Association
Attachment 9.7	Memorandum from Stuart Kurlander, Latham & Watkins, LLP, to Joan Dailey
Attachment 9.8	American Board for Certification in Orthotics and Prosthetics Closing Statement
Attachment 9.9	Memorandum of Agreement
Attachment 9.10	Public Comment Letters